



FORM PTO-1390 (Modified) (REV 11-2000)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER <b>221180US2PCT</b>	
<b>TRANSMITTAL LETTER TO THE UNITED STATES</b> <b>DESIGNATED/ELECTED OFFICE (DO/EO/US)</b> <b>CONCERNING A FILING UNDER 35 U.S.C. 371</b>				U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR <div style="font-size: 1.5em; font-weight: bold; text-align: center;">10/089149</div>	
INTERNATIONAL APPLICATION NO. <b>PCT/JP00/05295</b>		INTERNATIONAL FILING DATE <b>08 AUGUST 2000</b>		PRIORITY DATE CLAIMED <b>30 SEPTEMBER 1999</b>	
TITLE OF INVENTION <b>STETHOSCOPE</b>					
APPLICANT(S) FOR DO/EO/US <b>Tsutomu NAKADA</b>					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:					
<ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.</li> <li>4. <input checked="" type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31).</li> <li>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c) (2))           <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input checked="" type="checkbox"/> has been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ol> </li> <li>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).           <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is attached hereto.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</li> </ol> </li> <li>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))           <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</li> <li>b. <input type="checkbox"/> have been communicated by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input checked="" type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).</li> <li>10. <input checked="" type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).</li> <li>11. <input checked="" type="checkbox"/> A copy of the International Preliminary Examination Report (PCT/IPEA/409).</li> <li>12. <input checked="" type="checkbox"/> A copy of the International Search Report (PCT/ISA/210).</li> </ol>					
<b>Items 13 to 20 below concern document(s) or information included:</b>					
<ol style="list-style-type: none"> <li>13. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</li> <li>14. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</li> <li>15. <input type="checkbox"/> A <b>FIRST</b> preliminary amendment.</li> <li>16. <input type="checkbox"/> A <b>SECOND</b> or <b>SUBSEQUENT</b> preliminary amendment.</li> <li>17. <input type="checkbox"/> A substitute specification.</li> <li>18. <input type="checkbox"/> A change of power of attorney and/or address letter.</li> <li>19. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.</li> <li>20. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</li> <li>21. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</li> <li>22. <input type="checkbox"/> Certificate of Mailing by Express Mail</li> <li>23. <input checked="" type="checkbox"/> Other items or information:           <div style="margin-left: 20px; padding-top: 5px;"> <b>Notice of Priority / PCT/IB/304 / PCT/IB/308</b>  <b>PTO-1449 / Drawings (2 sheets)</b>  <b>Amended Sheets (pages 3, 3a, 12 &amp; 12a)</b> </div> </li> </ol>					

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.01/089149)		INTERNATIONAL APPLICATION NO. PCT/JP00/05295		ATTORNEY'S DOCKET NUMBER 221180US2PCT	
24. The following fees are submitted: <b>BASIC NATIONAL FEE ( 37 CFR 1.492 (a) (1) - (5)) :</b> <input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO . . . . . \$1040.00 <input checked="" type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO . . . . . \$890.00 <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO . . . . . \$740.00 <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) . . . . . \$710.00 <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) . . . . . \$100.00 <b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>				<b>CALCULATIONS PTO USE ONLY</b>	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).				\$890.00	
				\$0.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	5 - 20 =	0	x \$18.00	\$0.00	
Independent claims	1 - 3 =	0	x \$84.00	\$0.00	
Multiple Dependent Claims (check if applicable). <input type="checkbox"/>				\$0.00	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$890.00</b>	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27). The fees indicated above are reduced by 1/2.				\$0.00	
<b>SUBTOTAL =</b>				<b>\$890.00</b>	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).				\$0.00	
<b>TOTAL NATIONAL FEE =</b>				<b>\$890.00</b>	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). <input type="checkbox"/>				\$0.00	
<b>TOTAL FEES ENCLOSED =</b>				<b>\$890.00</b>	
				Amount to be: refunded	\$
				charged	\$
a. <input checked="" type="checkbox"/> A check in the amount of <u>\$890.00</u> to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>15-0030</u> A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO:					
 <b>22850</b> Surinder Sachar Registration No. 34,423 (703) 413-3000			<div style="text-align: right;">             SIGNATURE  <b>Marvin J. Spivak</b>            NAME  <b>24,913</b>            REGISTRATION NUMBER  <div style="text-align: right;"> <u>March 27 2002</u>              DATE           </div> </div>		

2/p1b

## DESCRIPTION

### STETHOSCOPE

### TECHNICAL FIELD

The present invention relates to a stethoscope, which is an instrument used by doctors in medical settings.

### BACKGROUND ART

Techniques for acquiring data regarding hemoglobin of an organism by use of near-infrared light have been well known (in general, such techniques are collectively called "near-infrared spectroscopy (NIRS)").

One example application thereof is an oxymeter, which has been widely used. In recent years, functional imaging for noninvasively detecting cerebral function through detection of a change in the cerebral circulation blood flow has been widely noticed. This technique has been widely used in, for example, positron emission tomography (PET), which utilizes water labeled with  $O^{15}$ , and in a magnetic resonance imaging (BOLD-fMRI) which utilizes the magnetic susceptibility effect of deoxy hemoglobin. Development of a functional imaging technique (called optical CT) which utilizes near-infrared light has been pursued, because such functional imaging enables obtainment of hemoglobin information by use of near-infrared light. However, this functional imaging technique cannot be said to have been

established.

Diagnostic apparatuses and tools can be divided into the following three categories.

(1) A large apparatus such as those used in connection with the above-mentioned PET and MRI, which requires a patient to go to a place where the apparatus is installed in order to receive an examination.

(2) A small apparatus, such as an electrocardiograph, an electroencephalograph, or an oxymeter, which is disposed at a bedside or in an ambulance, or a portable apparatus which is transported to the location of a patient.

(3) An instrument, such as a stethoscope, which a medical worker always carries on his person.

#### DISCLOSURE OF THE INVENTION

To date, the stethoscope is the only useful instrument which is categorized in the above-mentioned category (3). Meanwhile, in the above-mentioned category (2), apparatuses, such as an oxymeter, which utilize the above-described near-infrared light have been established. The concept of optical CT belongs to the above-mentioned category (1) or (2).

In view of the forgoing, an object of the present invention is to provide a simple, always-portable stethoscope for enabling accurate diagnosis.

In order to achieve the above object, the present invention provides the following:

[1] A stethoscope which comprises a probe section for

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noninvasively irradiating a diseased part with near-infrared light, the probe having radiation and light-receiving fibers; a control device connected to the probe section via a lead wire, the control device including a semiconductor laser light source connected to the radiation fiber, an optical detector connected to the light-receiving fiber, a controller for detecting a change in cerebral circulation blood flow on the basis of data output from the probe section, and a sound source device for converting the change in cerebral circulation blood flow to sound pulses; and a pair of lead wires and receivers connected to the sound source device of the control device, wherein auscultation is performed on the basis of the sound pulses from the sound source device in order to diagnose a change in cerebral function.

[2] A stethoscope according to [1] above, wherein the near-infrared light includes two wavelengths.

[3] A stethoscope according to [1] above, wherein the near-infrared light includes three wavelengths.

[4] A stethoscope according to [3] above, wherein the near-infrared light includes wavelengths of 760 nm, 800 nm, and 830 nm.

[5] A stethoscope according to [1] above, wherein the change in cerebral circulation blood flow is a change in total hemoglobin (t-Hb) or oxygen saturation rate of hemoglobin (rSO<sub>2</sub>).

The present invention enables provision of a "functional stethoscope" which noninvasively radiates near-

infrared light to a diseased part, and detects a change in the cerebral circulation blood flow, for example. The change is heard as sound pulse modulation to examine a change in the cerebral function. More specifically, a light beam of three wavelengths  $\lambda = 760, 800, 830$  nm which is generated by a semiconductor laser light source is applied to a diseased

part; and a change in reflection data is converted to a change in pulse frequency of the sound of constant pitch and volume, to thereby enable a doctor to carry out auscultation.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic structural view of a stethoscope according to an embodiment of the present invention.

FIG. 2 is a block diagram of the stethoscope according to the embodiment of the present invention.

FIG. 3 is a structural view of a radiation/light-receiving fiber of a probe section of the stethoscope according to the embodiment of the present invention.

FIG. 4 is a graph showing examples of activation by higher-order cerebral activities.

#### BEST MODE FOR CARRYING OUT THE INVENTION

An embodiment of the present invention will next be described in detail.

A stethoscope of the present invention is adapted to detect a change in total hemoglobin (t-Hb) or oxygen saturation (regional oxygen  $O_2$  saturation ( $rSO_2$ )) of hemoglobin and output the change in the form of sound information. The stethoscope of the present invention can be integrated with an ordinary stethoscope to thereby constitute a "smart stethoscope."

The stethoscope of the present invention is mainly used as a "functional stethoscope" which can confirm a local

activation caused by cerebral function. However, the stethoscope can be used in all medical fields in which detection of a change in t-Hb or rSO<sub>2</sub> is useful. Further, application of the stethoscope of the present invention, which is a portable instrument, is expected to expand to fields which cannot be conceived presently, as has been the case with the classical stethoscope, for which doctors have found a large number of applications throughout the years, even though the classical stethoscope is an instrument which detects "sound" only.

Near-infrared spectroscopy is a technique based on the phenomenon that biological tissue exhibits optical absorbency peculiar to a constituent substance thereof. In an application for human tissue, use of light in a wavelength range of 690 nm to 880 nm, which is hardly affected by water molecules or C-H bonds, is particularly effective. Light in this region (near-infrared region) can reach a point several centimeters deep from the surface of the body. This holds true in the case of the head (brain) which is surrounded by a cranial bone. A certain substance present in a living body has a property such that its optical absorbency changes greatly with the oxygen saturation thereof, and this property enables quantification of the oxygen saturation.

Representative examples of such a substance include hemoglobin, myoglobin, and cytochrom aa3. Theoretically, accurate analysis of these substances is possible. However, in principle, the present invention is directed to hemoglobin



analysis without accurate quantification.

The following description of the present invention is confined to hemoglobin.

Actual optical absorbency, which is detected through sensing of reflection of radiated light, changes in accordance with the total hemoglobin t-Hb and the oxygen saturation rate of hemoglobin in a tissue under examination. Accordingly, detection of optical absorbency at a single wavelength cannot determine whether the total hemoglobin or the oxygen saturation rate changes. In view of the foregoing, optical absorbency is detected by use of at least two different wavelengths, and both the total hemoglobin and the oxygen saturation rate are estimated. In actuality, more accurate values can be calculated by use of three wavelengths. However, satisfactory results are obtained by use of two wavelengths, and in some cases use of two wavelengths is more advantageous than use of three wavelengths. Hereinafter, the embodiment will be described with reference to a calculation formula for the case in which three wavelengths are used.

One important application of the present invention is determination of "cerebral function." In the brain, cerebral functions are present in a localized manner. That is, a certain function is allocated to a certain site of the brain. At the certain site of the brain used, various metabolic changes (e.g., an increase in blood flow rate or an increase in glucose consumption) occurs. Such metabolic changes which occur at specific brain sites due to specific activities are

collectively called "activation".

FIG. 4 shows an example of activation accompanying higher-order cerebral activities. This example was obtained by detecting, by means of near flared spectroscopy, changes in the oxygen saturation rate ( $rSO_2$ ) of hemoglobin in a dorsolateral prefrontal (DLPF) portion of a patient performing a graphical test. The graph shows that a certain site of the brain is activated by the activity, and  $rSO_2$  increases. During the periods between the arrows (start, stop) in FIG. 4, the patient performs the test, and the actual value of  $rSO_2$  rises and falls with a slight delay.

Use of the stethoscope of the present invention enables a user to determine such activation at the patient's bedside by listening to a sound.

That is, near-infrared light of two or three wavelengths is radiated onto the brain, light reflected therefrom is sensed, and the absorbency is estimated roughly; the precise quantity of the absorbency is not obtained. The roughly estimated absorbency is converted to a sound by means of a sound source device to thereby enable diagnosis by use of the stethoscope.

Next, a specific example of the present invention will be described.

Considered here is change in the total hemoglobin, which can be obtained by an approximate expression as follows (other methods may be employed when three wavelengths are used):

$$\Delta t\text{-Hb} = 1.6 \cdot \Delta A_{780} - 5.8 \cdot \Delta A_{800} + 4.2 \cdot \Delta A_{830}.$$

Similarly, change in  $r\text{SO}_2$  can be obtained by an approximate expression, as follows:

$$\Delta r\text{SO}_2 = (-3.0 \cdot \Delta A_{800} + 3.0 \cdot \Delta A_{830}) / (1.6 \cdot \Delta A_{780} - 2.8 \cdot \Delta A_{800} + 1.2 \cdot \Delta A_{830}).$$

In the expressions, each of the subscripts represents a corresponding wavelength of near-infrared light (nm). By changeover of a changeover switch, the total hemoglobin (t-Hb) or the oxygen saturation rate ( $r\text{SO}_2$ ) of hemoglobin can be measured selectively.

FIG. 1 is a schematic structural view of a stethoscope according to an embodiment of the present invention. FIG. 2 is a block diagram of the stethoscope. FIG. 3 is a structural view of a radiation/light-receiving fiber of a probe section of the stethoscope.

In these drawings, reference numeral 11 denotes a radiation/light-receiving fiber which serves as a probe section; 12 and 13 each denote an optical amplifier; 15 denotes a lead wire; 21 denotes a control device; 22 denotes a semiconductor laser source; 23 denotes a calibration control device; 24 denotes an optical detector; 25 denotes a data processing device (IC); 26 denotes a sound source device; and 27 denotes a changeover switch. Through use of this changeover switch 27, one of total hemoglobin (t-Hb) or the oxygen saturation rate ( $r\text{SO}_2$ ) of hemoglobin is selected as a value to be detected. In the drawing, a power source is omitted. Reference numeral 31 denotes a lead wire connected

to the sound source device 26; and 32 denotes a receiver which a doctor uses to hear sound.

As shown in FIG. 3, the radiation/light-receiving fiber which serves as a probe section of the stethoscope has a configuration such that a radiation fiber is disposed at the center, and reception fibers are disposed around the radiation fiber.

Diagnosis by use of the stethoscope is carried out as follows. That is, light of three wavelengths ( $\lambda = 760, 800, 830$  nm) is radiated to a diseased portion; and the control device 21 outputs a change in the reflection data. The sound source device 26 converts the change to a change in pulse frequency of a sound having a constant pitch and volume. A doctor listens to the sound from the receiver 32.

A specific operation of the sound source device 26 will now be described.

FIG. 4 shows changes in the  $rSO_2$  signal in the form of a graph. In the present invention, this change (in actuality, change in the selected one of t-Hb and  $rSO_2$ ) is indicated in the form of sound (similar to conversion between a diaphragm type and a bell type of an ordinary stethoscope).

In general, the following methods are used in order to indicate increase and decrease of a measured value by means of sound.

- (1) Increase the volume of sound.
- (2) Increase the pitch of sound.

However, both are difficult to sense.

In view of the foregoing, in the present invention, rise and fall of a measured value is converted to a change in the pulse frequency of a certain sound. In other words, the above conversion is similar to conversion from an "amplitude-modulated" signal to a "frequency-modulated" signal. That is, the pulse frequency of a certain sound is changed in accordance with a measured value as follows (Pi represents a sound):

Pi      Pi      Pi      Pi  
 Pi Pi Pi Pi Pi Pi Pi

In this case, the latter shows that the measured value has increased.

In consideration of the psychological resolution of a medical worker, the sound source device 26 outputs not a sound used in a conventional oxymeter or the like but a sound having a constant pitch and roundness (sound corresponding to action potential in physiology). A change in t-Hb or rSO<sub>2</sub> is converted to a change in pulse frequency of sound (as in the case of neuron firing rate), and a medical worker detects the change by listening to the sound.

As described above, the stethoscope of the present invention is a useful, always-portable type instrument, which has not been introduced to doctors or other medical personnel since the invention of the classical stethoscope. The importance of the present invention is remarkable in consideration of the role which classical stethoscopes, which convey sound information only, have played in the medical

field, and in view that the classical stethoscope is still the most important instrument used for diagnosis.

The present invention is not limited to the embodiments described above. Numerous modifications and variations of the present invention are possible in light of the spirit of the present invention, and they are not excluded from the scope of the present invention.

As described in detail, the present invention can provide a simple, always-portable stethoscope for enabling accurate diagnosis.

#### INDUSTRIAL APPLICABILITY

The present invention is suitable for the field of medical auscultatory devices, and can be applied to a functional stethoscope which enables a user to confirm a local activation caused by a cerebral function at a bedside.

## CLAIMS

1. (amended) 1. A stethoscope comprising:

(a) a probe section for noninvasively irradiating a diseased part with near-infrared light, the probe having radiation and light-receiving fibers;

(b) a control device connected to the probe section via a lead wire, the control device including a semiconductor laser light source connected to the radiation fiber, an optical detector connected to the light-receiving fiber, a controller for detecting a change in cerebral circulation blood flow on the basis of data output from the probe section, and a sound source device for converting the change in cerebral circulation blood flow to sound pulses; and

(c) a pair of lead wires and receivers connected to the sound source device of the control device, wherein

(d) auscultation is performed on the basis of the sound pulses from the sound source device in order to diagnose a change in cerebral function.

2. A stethoscope according to claim 1, wherein the near-infrared light includes two wavelengths.

3. A stethoscope according to claim 1, wherein the near-infrared light includes three wavelengths.

4. A stethoscope according to claim 3, wherein the near-infrared light includes wavelengths of 760 nm, 800 nm, and 830 nm.

5. A stethoscope according to claim 1, wherein the change in cerebral circulation blood flow is a change in total





## ABSTRACT

A simple always-portable stethoscope for enabling accurate diagnosis. A radiation/light-receiving fiber (11) serving as a probe part for noninvasively irradiating a diseased part with near-infrared light is applied to the diseased part so as to measure, e.g., a change of the cerebral circulation blood flow. The change is hard as sound pulse modulation to examine the change of the cerebral function. For example, a light beam of three wavelengths  $\lambda = 760, 800, 830$  nm from a semiconductor laser light source (22) is applied to the diseased part, the reflection data from the diseased part is processed by a control device (21), and the doctor can make a diagnosis with the doctor's ears by hearing with a receiver (32) the change as the change of the frequency of the sound the pitch and volume of which are constant.

FIG. 1

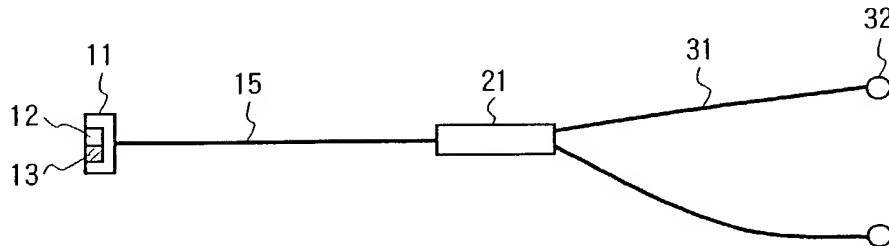


FIG. 2

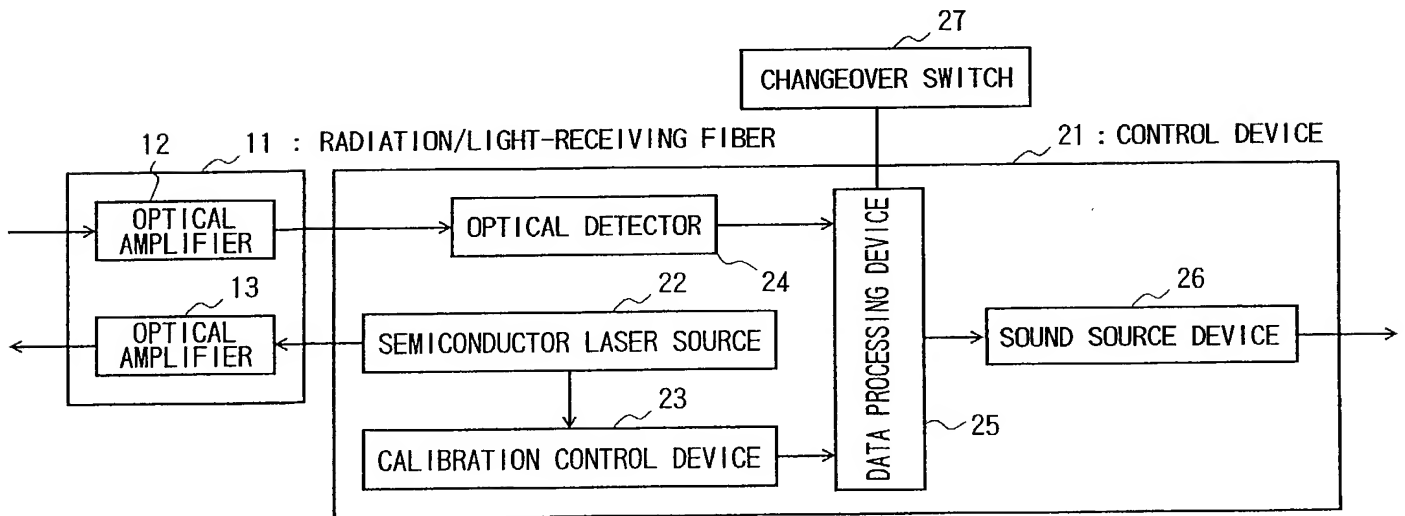


FIG. 3

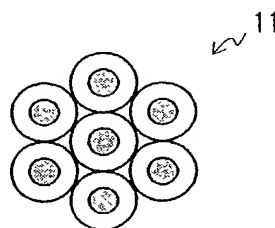
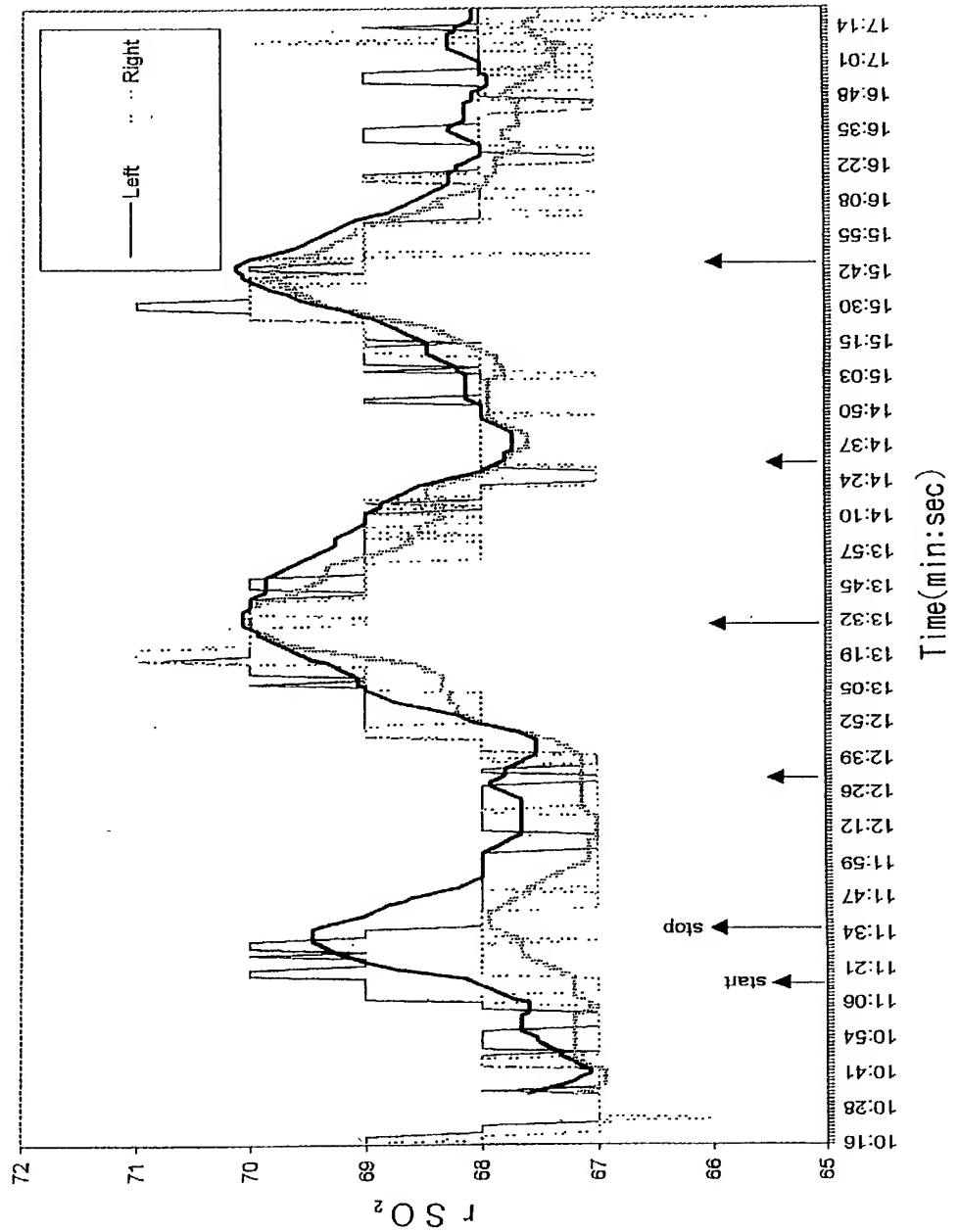


FIG. 4



# Declaration and Power of Attorney For Patent Application

## 特許出願宣言書及び委任状

### Japanese Language Declaration

#### 日本語宣言書

下記の氏名の発明者として、私は以下の通り宣言します。

As a below named inventor, I hereby declare that:

私の住所、私書箱、国籍は下記の私の氏名の後に記載された通りです。

My residence, post office address and citizenship are as stated next to my name.

下記の名称の発明に関して請求範囲に記載され、特許出願している発明内容について、私が最初かつ唯一の発明者（下記の氏名が一つの場合）もしくは最初かつ共同発明者（下記の名称が複数の場合）であると信じています。

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled.

STETHOSCOPE

上記発明の明細書は、

- ☐ 本書に添付されています。
- ☐ \_\_\_\_月\_\_\_\_日に提出され、米国出願番号または特許協定条約国際出願番号を\_\_\_\_とし、  
(該当する場合) \_\_\_\_に訂正されました。

the specification of which

- ☒ is attached hereto.
- ☒ was filed on August 8, 2000  
as United States Application Number or  
PCT International Application Number  
PCT/JP00/05295 and was amended on  
March 26, 2001 (if applicable).

私は、特許請求範囲を含む上記訂正後の明細書を検討し、内容を理解していることをここに表明します。

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

私は、連邦規則法典第37編第1条56項に定義されるとおり、特許資格の有無について重要な情報を開示する義務があることを認めます。

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

# Japanese Language Declaration (日本語宣言書)

私は、米国法典第35編119条 (a) - (d) 項又は365条 (b) 項に基づき下記の、米国以外の国の少なくとも一カ国を指定している特許協力条約365 (a) 項に基づく国際出願、又は外国での特許出願もしくは発明者証の出願についての外国優先権をここに主張するとともに、優先権を主張している、本出願の前に出願された特許または発明者証の外国出願を以下に、枠内をマークすることで、示しています。

Prior Foreign Application(s)

外国での先行出願

<u>11-278605</u>	<u>Japan</u>
(Number)	(Country)
(番号)	(国名)
 (Number)	 (Country)
 (番号)	 (国名)

私は、第35編米国法典119条 (e) 項に基づいて下記の米国特許出願規定に記載された権利をここに主張いたします。

<u>(Application No.)</u>	<u>(Filing Date)</u>
(出願番号)	(出願日)

私は、下記の米国法典第35編120条に基づいて下記の米国特許出願に記載された権利、又は米国を指定している特許協力条約365条 (c) に基づく権利をここに主張します。また、本出願の各請求範囲の内容が米国法典第35編112条第1項又は特許協力条約で規定された方法で先行する米国特許出願に開示されていない限り、その先行米国出願書提出日以降で本出願書の日本国内または特許協力条約国際提出日までの期間中に入手された、連邦規則法典第37編1条56項で定義された特許資格の有無に関する重要な情報について開示義務があることを認識しています。

<u>(Application No.)</u>	<u>(Filing Date)</u>
(出願番号)	(出願日)

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私は、私自信の知識に基づいて本宣言書中で私が行なう表明が真実であり、かつ私の入手した情報と私の信じているところに基づく表明が全て真実であると信じていること、さらに故意になされた虚偽の表明及びそれと同等の行為は米国法典第18編第1001条に基づき、罰金または拘禁、もしくはその両方により処罰されること、そしてそのような故意による虚偽の声明を行なえば、出願した、又は既に許可された特許の有効性が失われることを認識し、よってここに上記のごとく宣誓を致します。

I hereby claim foreign priority under Title 35, United States Code, Section 119 (a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed.

	Priority Claimed 優先権主張
<u>30 / SEPTEMBER / 1999</u>	<input checked="" type="checkbox"/> <input type="checkbox"/>
(Day/Month/Year Filed)	Yes No
(出願年月日)	はい いいえ
 (Day/Month/Year Filed)	<input type="checkbox"/> <input type="checkbox"/>
(出願年月日)	Yes No
	はい いいえ

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below.

<u>(Application No.)</u>	<u>(Filing Date)</u>
(出願番号)	(出願日)

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code Section 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of application.

<u>(Status: Patented, Pending, Abandoned)</u>
(現況：特許許可済、係属中、放棄済)

<u>(Status: Patented, Pending, Abandoned)</u>
(現況：特許許可済、係属中、放棄済)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

